O *Ombudsman* do Paciente — A Experiência Norueguesa(*)

THE PATIENT OMBUDSMAN — THE NORWEGIAN SCHEME

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RESUMO

Para facilitar a implementação prática das leis referentes aos direitos dos pacientes, alguns países na Europa criaram o sistema de *Ombudsman* do Paciente. A Noruega foi uma das primeiras nações a adotar essa figura, há 20 anos, e hoje, conta com um *ombudsman* em todos os 19 condados (estados). A partir de 2001, a instituição do *Ombudsman* do Paciente adquiriu bases legais com o Decreto dos Direitos dos Pacientes. O papel principal deste profissional é o de salvaguardar os pacientes e contribuir para a melhoria da qualidade dos serviços de saúde. Para tanto, oferece orientações, ajuda a esclarecer questões de saúde e apresenta casos para as autoridades públicas e para o sistema econômico de compensação. Com base na experiência européia e, em particular, norueguesa, este artigo discute a estrutura organizacional, papéis e funções do esquema de *Ombudsman* do Paciente.

Palavras-chave:

Direito dos Pacientes; Estado de Direito; Legislação em Saúde; Noruega.

ABSTRACT

To facilitate the practical implementation of patients' rights laws, some countries in Europe have developed Patient *Ombudsman* systems. About 20

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years ago, Norway was one of the first countries to introduce this arrangement. Nowadays, the country has *Ombudsmen* in each of its 19 counties. Since 2001 the Patient *Ombudsman* institution got its legal basis through the Act on Patients' Rights. The main role of this professional is to safeguard patients and to contribute to the improvement of health services quality. In order to realize that *Ombudsmen* give guidance, help patients having their problems clarified with the health service and bring cases to the supervisory authority and to the system for economic compensation. Based on European and in particular Norwegian experience, this article discuss the organizational structure, role and functions of the Patient *Ombudsman* scheme.

Key words

Health Legislation; Norway; Patients' Rights; Rule of Law.

1. INTRODUÇÃO

A palavra "*ombudsman*", de origem escandinávia, foi introduzida no vocabulário há cerca de 300 anos e é utilizada para identificar a pessoa que tem o direito e o poder de falar em nome de outra pessoa. Muitos países, de acordo com suas próprias tradições e valores, desenvolveram uma determinada estrutura administrativa com direitos e poderes diferenciados para proteger o cidadão diante do poder público.

O ministro norueguês para Assuntos Sociais, em discurso ao Parlamento em 1975, afirmou que todo paciente em instituições de saúde deveria ter um *ombudsman* especial para quem pudessem ser feitas reclamações. Nenhuma decisão foi tomada naquela ocasião. Mas, a partir da metade da década de 80, os 19 condados (estados) da Noruega iniciaram, por conta própria, um processo de criação de um sistema chamado *ombudsmam* do Paciente, para dar um apoio especial às pessoas doentes. Em 1999, o Decreto dos Direitos dos Pacientes foi promulgado e o *ombudsman* ganhou bases legais.

Para compreender os direitos e poderes do *ombudsman* é importante contextualizar o cenário de trabalho deste profissional. O presente trabalho inicia-se com uma descrição do sistema de saúde norueguês, a legislação em saúde e alguns dos mais relevantes processos referentes aos serviços de saúde. As funções do *ombudsman* também são analisadas sob a ótica do *Ombudsman* Parlamentar.

1.1. O sistema de saúde

A Noruega é um país de 4,5 milhões de habitantes, dividido em 19 condados, com uma população variando de 75 mil a 500 mil habitantes em cada condado. Estas áreas, por sua vez, são divididas em municípios (434 no total).

Os governos dos condados e das municipalidades são eleitos democraticamente. As autoridades nacionais são responsáveis pelo desenvolvimento de políticas públicas, pela legislação, orçamento e qualidade dos serviços de saúde. A Noruega é, em muitos sentidos, um país igualitário. O Estado financia o sistema de seguridade social que é usufruído por todos os cidadãos de uma maneira uniforme; todos os residentes têm direito aos mesmos serviços e estes devem ser oferecidos de maneira padronizada. Esta é a parte do programa nacional de bem-estar social que tem sido promovida nos últimos 50 anos.

Os municípios são responsáveis pelos cuidados primários, o que inclui médicos clínicos, parteiras, central de atendimento telefônico de emergência, atendimento domiciliar, enfermaria, fisioterapia e ações e serviços preventivos de saúde individuais e ambientais. Recentemente, foi implementado um sistema de cadastro de usuários por clínicos. O estado é responsável pelo atendimento especializado, que inclui hospitais psiquiátricos. Esta função é delegada para quatro empresas públicas regionais, cada uma com seu conselho. Os condados cuidam da saúde dental, especialmente das crianças, idosos e portadores de necessidades especiais.

Alguns clínicos são servidores públicos municipais e outros trabalham como contratados dos municípios. Quase todos os hospitais são públicos e os médicos e outros profissionais da saúde são funcionários. Os poucos hospitais privados trabalham como contratados das empresas públicas de saúde, assim como clínicas médicas. O serviço puramente privado representa uma pequena parte dentro do sistema de saúde norueguês.

1.2. Legislação em saúde

Todas as leis são promulgadas pelo Parlamento e, na prática, elas percorrem um longo caminho, até serem aprovadas, quando tratam de assuntos específicos. O governo, ou o ministério, pode definir regulamentações mais detalhadas sobre temas, caso a lei autorize explicitamente. Estas regulamentações complementam estatutos, especialmente em matérias técnicas, mas têm menor importância na legislação em saúde norueguesa.

A legislação está organizada em cinco áreas que regulam respectivamente:

— financiamento de serviços de saúde;

— as principais estruturas administrativas responsáveis pelos serviços de saúde e o conjunto mínimo de serviços a ser oferecido;

— a relação entre estas estruturas e os profissionais de saúde que atuam nelas;

— a relação entre estas estruturas e os pacientes/cidadãos;

— a relação entre os pacientes e os profissionais de saúde.

Em 2001, houve uma significativa reforma na legislação em saúde, com a introdução de um pequeno número de estatutos, sendo que cada um deles diz respeito a determinados elementos do sistema de saúde e sua operação. Coletivamente, eles cobrem quase todos os aspectos da saúde. Pode-se dizer que a Noruega conta com nove leis principais na área da saúde:

— Seguridade Social;

— Direitos dos Pacientes;

— Serviços Municipais de Saúde;

— Serviços Especializados em Saúde;

— Atendimento Mental em Saúde;

— Assistência Médica Individualizada;

— Doenças de Notificação compulsória;

— Supervisão;

— Compensação dos Pacientes.

1.3. Direitos dos Pacientes[1]

A legislação foi construída de acordo com os princípios de direitos e deveres para proteger os interesses dos pacientes[2]. Cidadãos e pacientes têm direitos. Aqueles que têm deveres, em correspondência a esses direitos, são os municípios, principalmente o Estado, e os diferentes grupos de assistência à saúde individual. Assim, o que é descrito como um direito dos pacientes é definido como um dever nas leis relacionadas aos serviços municipais, serviços de saúde secundários e individualizados. Embora alguns direitos possam ser considerados vagos, muitos são bastante específicos. O sistema de direito-dever dá espaço para pacientes que considerem

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(1) KJØNSTAD, A. The development of patients' rights in Norway. In: MOLVEN, O. (Ed). *The Norwegian Health Care system*: legal and organizational aspects. Oslo: University of Oslo, 1999. p. 125-140.
(2) MOLVEN, O. The guiding principles of Norwegian Health legislation. In: MOLVEN, O. (Ed). Health *Legislation in Norway*. Oslo: Ad Notam, 2002. p. 18-27.

que seus direitos foram infringidos. Estes casos são avaliados pelo Comitê de Vigilância em Saúde da Noruega ou pela justiça.

O conjunto dos direitos do paciente é especialmente definido pelo Ato dos Direitos dos Pacientes. Basicamente, eles têm o direito à consulta e tratamento, juntamente com a livre escolha do médico e do hospital. As leis que tratam do Atendimento Personalizado em Saúde, dos Serviços Municipais de Saúde e dos Serviços Especializados em Saúde estipulam a obrigação de que esses serviços tenham padrões mínimos de qualidade. Além disso, os pacientes têm o direito de participar nas decisões sobre o tratamento, de dar o consentimento informado para o tratamento médico, ter acesso aos registros médicos ter cópia de seus arquivos e o direito à confidencialidade médica. Um ponto importante a ser analisado neste artigo é o direito dos pacientes de exigirem o cumprimento de seus direitos, quando acreditam que eles tenham sido violados.

Desde 2004, o direito dos cidadãos ao tratamento hospitalar tem sido consideravelmente reforçado. Os hospitais não podem deixar de atender aos pacientes, que preenchem os critérios legais de avaliação e tratamento, em virtude da falta de capacidade. Caso não possam oferecer o tratamento em suas próprias instalações, as empresas públicas têm agora o dever de providenciar serviços de saúde especializados, encaminhando os pacientes para outras instituições e arcando com esses custos.

1.4. Estado de Direito

Para assegurar que as leis e os direitos sejam colocados em prática, foram elaboradas certas medidas.

Aqueles que fornecem serviços de saúde têm a obrigação de estabelecer um sistema de controle interno, o que significa criar medidas sistemáticas para certificar e documentar que as ações sejam realizadas de acordo com os requerimentos definidos pelas leis ou regulamentações. Este processo deve ser especificado em procedimentos administrativos.

A autoridade fiscalizadora — um comitê independente chamado de Comitê de Vigilância em Saúde da Noruega que inclui 18 agências em nível de condado — é responsável pela supervisão dos serviços e dos trabalhadores da saúde. Este comitê determina o sistema de controle interno dos fornecedores de saúde e os serviços a serem oferecidos de acordo com a lei.

Pacientes que achem que seus direitos não tenham sido cumpridos corretamente, segundo o Ato dos Direitos dos Pacientes, § 7-1, têm o direito de reivindicar que os prestadores de serviços revejam suas decisões. Os hospitais, por exemplo, têm o dever de responder a uma reivindicação desse tipo.

Em caso de vislação de direitos, os paciente podem se dirigir aos comitês de Vigilância em Saúde dos condados. Esta autoridade avalia o que aconteceu e tem o poder de reverter uma decisão feita pelo serviço de saúde ou por um médico. Em última instância, pode instituir procedimentos disciplinares.

Em casos de reivindicações de compensações financeiras, os pacientes devem apresentar o caso para o Sistema de Compensação de Pacientes, um órgão público imparcial responsável pelas indenizações.

Na estrutura do sistema de saúde da Noruega, há a figura do *ombudsman* parlamentar e a do *ombudsman* do condado como responsáveis pela proteção dos pacientes que necessitam de assistência para assegurar seus direitos dentro da saúde pública. Este profissional também auxilia os doentes a apresentarem suas reclamações junto ao Comitê de Vigilância em Saúde dos condados e ao Sistema de Compensação de Pacientes. Porém, antes de discutir o papel dos *Ombudsmen*, tratar-se-á das autoridades de vigilância em saúde e do sistema de compensação de pacientes e do *ombudsman* civil.

1.5. A vigilância em saúde[3]

O Comitê de Vigilância em Saúde da Noruega, liderado por um diretor geral, atua de maneira coordenada com a autoridade de vigilância e uma agência profissional, dentro do Ministério da Saúde. Este comitê é um órgão independente para avaliação de questões técnicas e o ministro não pode interferir no processo de administração dos casos sob a responsabilidade do comitê.

Os comitês de Vigilância em Saúde dos condados, coordenados pelo comitê nacional, são responsáveis pela supervisão dos serviços de saúde e pela assistência médica. Eles são dirigidos por médicos e seu corpo de funcionários é formado por diferentes tipos de profissionais médicos e advogados.

Os pacientes têm o direito, virtualmente, de acesso a todas as decisões tomadas pelos serviços de saúde e de assistência médica, relacionadas à informação e documentação, analisadas pelo Comitê de Vigilância em Saúde, de acordo com a Lei dos Direitos dos Pacientes, § 7-2:

> *"Se o fornecedor de serviços de saúde rejeita o pedido, ou se este fornecedor é da opinião de que os direitos já foram devidamente res-*

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(3) Disponível em: <http://www.helsetilsynet.no/templates/sectionpage____5499.aspx>http://www.helsetilsynet.no/templates/sectionpage____5499.aspx>.

peitados, uma reclamação pode ser submetida ao escritório médico local. A queixa deve ser encaminhada para o Comitê de Vigilância em Saúde do condado."

Os comitês de vigilância dos condados têm o poder e o dever de reverter qualquer decisão que não esteja de acordo com a lei. Decisões feitas pela autoridade de vigilância devem ser encaminhadas para a justiça.

Os pacientes têm o direito de ter seus casos avaliados mesmo quando não há uma ação específica para ser revogada. Os comitês dos condados devem sempre considerar o ponto de vista do paciente nestas situações e determinar se a lei foi respeitada, de acordo com o Ato de Assistência Médica Individualizada, § 55:

"Uma pessoa que considere que uma cláusula relativa aos deveres estipulados neste Ato foi quebrada em seu prejuízo, deve requerer uma tributação sobre esta matéria diante da autoridade de vigilância. O paciente deve agir por meio de um representante e a demanda deve ser encaminhada para os comitês de vigilância em saúde dos condados. Estes comitês devem considerar os argumentos da requisição e também encaminhar outros pontos além daqueles discriminados."

Finalizando, os comitês dos condados devem se pronunciar se a lei foi infringida ou não e, se necessário, devem orientar os serviços de saúde e de assistência médica.

Por sua vez, o Comitê de Vigilância em Saúde da Noruega é responsável pela coordenação de todas as autoridades fiscalizatórias para garantir que a aplicação da lei seja uniforme no país. Caso o escritório regional considere que houve negligência médica, conduta considerada ilegal pelo Ato de Assistência Médica individualizada, e que essa postura colocou em risco a segurança dos serviços de saúde ou implicou em algum grave prejuízo ao paciente, este escritório deve informar ao Comitê nacional. Nestes casos, o Comitê nacional pode advertir seriamente o profissional e, dependendo da gravidade da negligência, até mesmo, cassar sua licença para o exercício da profissão[4].

1.6. O sistema de compensação de paciente norueguês[5]

Esquema que cobre todos os pacientes em qualquer tipo de tratamento médico, seja ele realizado na rede pública ou na rede privada conveniada

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(4) MOLVEN, O. Reactions against health personnel that are not complying with the law. In MOLVEN, O. (Ed). *Health Legislation in Norway*. Oslo: Ad Notam, 2002. p. 124-136.
(5) JORSTAD, R. G. The Norwegian System of Compensation to Patients. *Medicine and Law*, v. 21, n. 4, p. 681-686, 2002.

ao poder público, o sistema de compensação de pacientes inclui cuidados médicos, de enfermagem, parteiras, dentistas, fisioterapeutas, farmácias e transporte por ambulância. A partir de 2008, todos os pacientes em tratamento na rede privada também receberão cobertura.

O objetivo principal dessa lei é determinar se o hospital ou médico cometeram alguma falha no atendimento ao paciente, mesmo que não seja considerado um erro. Há também circunstâncias descritas em lei que estabelecem a responsabilidade em situações em que não se configure um erro exatamente. Isto significa que se pode caracterizar este esquema como um equilíbrio entre um não-erro e uma má prática.

Para a indenização, é preciso provar uma relação causal entre o tratamento incorreto ou o diagnóstico e a injúria alegada. Porém, em algumas situações não é necessário *provar* a conexão causal. Como, por exemplo, estabelece o § 3 da lei de compensação:

> *"Se a causa do prejuízo ao paciente não pode ser estabelecida e o prejuízo pode ser provavelmente atribuído a uma influência externa durante o tratamento do paciente, deve se assumir que ele foi causado por um erro ou falha do fornecedor do serviço."*

Em casos nos quais a decisão não satisfaça ao paciente, ele pode apelar para um tribunal especial, ou até, para a justiça. Praticamente 10% dos casos seguem até o fórum especial e 1% até a justiça.

1.7. O ombudsman *civil*

O *ombudsman* para a Administração Pública da Assembléia (de agora em diante o "*ombudsman* civil") foi instituído em 1962; momento em que a administração pública já estava fortalecida, dentro de uma política de bem-estar social. A maioria dos cidadãos necessitava de se relacionar, de diferentes maneiras, com os poderes públicos e sentiam-se, freqüentemente, enfraquecidos diante de uma organização tão gigante. Embora os noruegueses tradicionalmente confiem nas autoridades públicas, pelo menos em comparação com outros países, pareceu necessário oferecer, ao cidadão, maneiras mais diretas de controlar estas autoridades. Era preciso um órgão independente para encampar investigações sem recorrer às prolongadas batalhas judiciais.

A tarefa do *ombudsman* civil é a de evitar que injustiças sejam cometidas pela administração pública, servidores ou prestadores de serviços públicos contra o indivíduo. A intervenção do *ombudsman* civil pode acontecer em razão de uma queixa ou por iniciativa própria. Qualquer pessoa que se sinta objeto de alguma injustiça, por parte do poder público, tem o direito de encaminhar sua reclamação ao *ombudsman*, assim também como qual-

quer cidadão que tenha sido privado de sua liberdade. O *ombudsman* emite um parecer e a autoridade pública deve se posicionar com relação a essa solicitação.

Em meados de 1980, as queixas relativas aos serviços de saúde representavam menos de 50 casos (menos de 2% do total) encaminhados ao *ombudsman* civil. Considerando a importância dos serviços de saúde dentro da administração pública como um todo, o *ombudsman* tinha um papel relativamente secundário em assegurar o Estado de Direito aos pacientes. Por esta razão, o sistema de *ombudsman* do paciente foi criado e, em pouco tempo, já contava com vários casos relacionados com a prestação de serviços em saúde.

1.8. O Ombudsman do paciente

Os direitos dos pacientes desenvolveram-se durante os anos 80 como um conceito central dentro do debate público sobre pesquisa, administração da saúde e justiça, na Noruega. A concepção destes direitos teve conotações particularmente positivas e ganhou considerada importância dentro das políticas de saúde. Todos os 19 condados, responsáveis pela atenção à saúde secundária, incluindo os hospitais, adotaram "voluntariamente" o sistema de *ombudsman*.

Nas diretivas regionais, o *ombudsman* goza de certa autonomia profissional e não pode ser pressionado pela administração do condado ou a direção do hospital.

No final dos anos 90, o sistema de *ombudsman* do paciente recebia cerca de 5 mil requisições anualmente. Na capital, Oslo, organizou-se um esquema especial que incluía também o atendimento a queixas relativas ao sistema primário em saúde.

Entre os condados, havia variações quanto ao papel do *ombudsman*, que poderia ser de "repórter", "porta-voz" ou "advogado", além de "intermediário", algumas vezes de "conselheiro espiritual" ou mesmo de "faz-tudo".

Entre os anos 80 e 90, alguns sistemas regionais de *ombudsman* foram avaliados, apontando um futuro para esta organização[6]:

> "O objetivo do *ombudsman* do paciente deve ser o de proteger os interesses dos pacientes e seus direitos legais, colaborando também para a melhoria do sistema de saúde. No futuro, este sistema deve (também):
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> — ser regulado pela lei;
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> — atuar exclusivamente no sistema de saúde;

(6) MOLVEN, O. The Patient *Ombudsman* Scheme — A Contribution to Legal Safeguards and Quality in the Health Service? *Lov og Rett (Norwegian Law Journal)*, 1991. p.195-222.

— ser gratuito;

— ser organizado regionalmente;

— ter autonomia;

— e ter competência legal."

A partir de 2001, a instituição do *ombudsman* do paciente passou a contar com base legal, com a publicação do Ato dos Direitos dos Pacientes. Atualmente, são encaminhadas cerca de 11 mil reclamações para os *ombudsmen* por ano.

A seguir, examinaremos o sistema de *ombudsman* do paciente.

2. A ESTRUTURA ORGANIZACIONAL

2.1. Base legal

O Capítulo 8 do Ato dos Direitos dos Pacientes destaca o objetivo, escopo e poderes do *ombudsman* dos pacientes. O sistema é mais detalhado na proposição apresentada pelo Ministério ao Parlamento *(Odelsting)*[7] e na recomendação do comitê de saúde à mesma Assembléia[8]. O Ministério da Saúde também tem competência para definir regulações.

2.2. Nível das funções

O sistema de *ombudsman* do paciente, como mencionado, foi estabelecido em nível regional, em cada condado. A partir de 2002, ele se tornou uma instituição nacional. O governo é responsável por assegurar, de acordo com o § 8-2, que: *"Todo condado tenha um ombudsman"*. As pessoas de uma determinada região, ou que estejam recebendo um cuidado de saúde em determinada região, devem se encaminhar para o *ombudsman* do condado em particular.

O *ombudsman* do paciente e o civil operam em diferentes níveis. O civil atua no Parlamento, localizado em Oslo, capital da Noruega, e todo o país está sob sua jurisdição. Os 19 *Ombudsmen* dos condados fazem parte do Ministério da Saúde e permanecem em cada um dos 19 condados, tendo como foco os serviços de saúde da população local.

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(7)<Proposição n. 12 (1998-99) do Odelsting (Parlamento). About the Act on Patients' Rights, chapter 8.

(8) Recomendação n. 91 (1998-99) do Odelsting (Parlamento). The Act on Patients' Rights.

2.3. Localização e recursos humanos

Os *ombudsmen* dos pacientes, usualmente, atuam nas maiores cidades dos condados, normalmente onde também estão situados os grandes hospitais, sendo que alguns escritórios são, inclusive, localizados dentro destas instituições.

Nos pequenos condados existe apenas um *ombudsman*; outros contam com dois profissionais. Oslo mantém dez *ombudsmen* e, até por esta razão, eles passaram a responder pelos cuidados do sistema primário de saúde.

O *ombudsman* não exerce nenhuma outra atividade, evitando conflitos de interesses. Usualmente, é um advogado; os profissionais de saúde que exercem essa função recebem um treinamento sobre legislação.

2.4. Organização orçamentária

O ombudsman *é responsabilidade do Estado que também decide quantos profissionais farão parte da instituição. Não há regras fixas para isso e o serviço é gratuito para toda a população.*

2.5. Regulação e responsabilidades

O *ombudsman* deve exercer suas atividades de maneira autonôma e independente do Ministério ou de outra instituição pública, como prevê o § 8-2: *"O ombudsman deve realizar seu trabalho independentemente."* A Assembléia enfatiza esta noção em seus comentários à lei. Assim, é claro que ninguém pode afetar o *ombudsman* na avaliação dos casos e a prática tem mostrado que o Ministério não tenta influenciar este profissional.

Com relação às regulamentações, define o § 8-8: *"O Ministério pode publicar regulações sobre a implementação das cláusulas relacionadas ao* ombudsman *do paciente e pode também complementar essas cláusulas."*

As orientações são relativas apenas às questões organizacionais e administrativas, como demandas de recursos humanos e treinamentos.

2.6. Discussão

A estrutura organizacional do sistema de *ombudsman* do paciente foi estabelecida de várias formas. Há uma base legal para este sistema, existe clareza sobre as funções e a organização orçamentária e não há dúvidas de

que o *ombudsman* trabalha de forma independente. Porém, pode ser um desafio para a autonomia deste sistema estar subordinado ao Ministério da Saúde, especialmente porque este órgão também tem como responsabilidade organizar os serviços secundários de saúde. Contudo, como foi definida independência do *ombudsman* não há razão para temer que as autoridades públicas tentem influenciar suas decisões.

3. PAPEL E FUNÇÕES

3.1. Objetivos

O objetivo da instituição do *ombudsman* do paciente é definido no § 8-2: "*O* ombudsman *do paciente deve proteger os direitos legais e interesses dos pacientes em sua relação com o serviço de saúde e melhorar a qualidade do serviço*". O *ombudsman* é conseqüentemente visto como uma importante instituição tanto na defesa do Estado de Direito, como na melhoria da qualidade do sistema.

Este profissional, segundo o Parlamento, deve agir de diferentes formas para alcançar esses objetivos. Deve dar encaminhamento às queixas feitas pelos cidadãos e também deve agir por iniciativa própria, atuando em casos de seu conhecimento. Também se espera que o *ombudsman* alimente os serviços de saúde com a experiência adquirida.

O *ombudsman* deve ser um intermediador para as queixas dos pacientes diante das instâncias legais e, em conjunto com este mesmo paciente, determinar para onde endereçar as reivindicações, como, por exemplo, o Comitê Nacional de Vigilância em Saúde ou o Sistema de Compensação dos Pacientes.

Ainda, de acordo com o § 8-1, o *ombudsman* deve trabalhar com as necessidades e interesses dos pacientes, em bases gerais, assim como trabalhar com os "*direitos legais*"(9). O foco deve ser tanto o paciente individual, como a coletividade. Também é previsto que o *ombudsman* contate os serviços de saúde e lhes dê retorno sobre as experiências e opiniões dos pacientes.

3.2. Funções

A função do *ombudsman* do paciente inclui apenas os serviços de saúde secundários e este profissional não deve atuar no serviço primário ou

(9) Sobre as diferentes formas de participação dos *ombudsmen* na garantia dos direitos dos pacientes em outros países ver SEGEST, E. The Ombudsman's involvment in ensuring patients' rights. *Medicine and Law*, v. 16, n. 3, p. 473-486, 1997 and FALLBERG, L.; MACKENNEY, S. Patient *Ombudsman* in seven European Countries: an Effective Way to Implement Patients' Rights? *Journal of Health Law*, v. 10, p. 343-357, 2003.

nos especialistas privados. Porém, os pacientes que não estiverem satisfeitos com esses setores podem obter informações legais junto aos *Ombudsmen*. Usualmente, o comitê de vigilância em saúde do condado é a instância apropriada para essas queixas.

Os Atos dos Direitos dos Pacientes, de Serviços Especializados em Saúde, da Saúde Mental e o da Assistência Médica Individualizada são relevantes para o segmento secundário da saúde. A questão é levantar, de um lado, se os direitos dos pacientes foram violados e, de outro lado, se as administrações públicas cumpriram seus deveres. Também existem os casos nos quais os pacientes podem receber indenizações, de acordo com o Decreto de Compensação dos Pacientes.

3.3. Tarefas

As principais tarefas do *ombudsman* são aconselhar e orientar os pacientes, quando solicitado. Isso significa que sua principal atividade é a de informar aos pacientes seus direitos e deveres e os caminhos legais a seguir. A assistência inclui também, por exemplo, o apoio aos pacientes, caso necessário, em seus contatos com a administração pública.

Além disso, inclui endereçar as queixas informalmente, solicitando aos serviços de saúde que atendam aos interesses dos pacientes, ou formalmente, por exemplo, solicitando à autoridade fiscalizadora para reverter uma decisão e/ou para disciplinar um integrante da equipe da instituição, ou da própria instituição.

Está explícito na legislação que o ombudsman deve apresentar sugestões para melhorar a qualidade dos serviços de saúde, envolvendo também os hospitais nesse trabalho.

O *ombudsman* do paciente deve sempre divulgar suas decisões, como estabelece a subseção segunda do § 8-7, *"O* ombudsman *do paciente é encarregado de opinar sobre assuntos relacionados ao seu trabalho e de sugerir medidas concretas de melhorias. O* ombudsman *deve decidir, por conta própria, para quem suas análises devem ser encaminhadas"*. Este poder de fornecer informações a quem ache de direito fortalece o papel do *ombudsman* como um importante órgão de introdução de soluções e melhorias.

O *ombudsman* não pode fazer nada contra a vontade do paciente. Assim, se um cidadão, por exemplo, não quiser encaminhar sua queixa para a autoridade fiscalizadora, o *ombudsman* deve respeitar esse desejo, mesmo que seja óbvio que o paciente ganharia o caso. Porém, ele deve utilizar o caso, de maneira anônima, se se tratar de uma situação que, de uma perspectiva geral, for importante. Em alguns casos, ele deve reportar o caso para o Comitê de Vigilância em Saúde.

Quando os casos são finalizados, o *ombudsman* deve informar aos pacientes sobre os resultados e suas razões.

Em algumas situações, a autoridade pública da saúde deve ser informada como prevê a subseção 4 do § 8-7: *"O ombudsman do paciente deve notificar as autoridades fiscalizadoras em situações nas quais um acompanhamento destas autoridades é necessário."* Na prática, as autoridades acompanham casos envolvendo negligência que resultem em sérios prejuízos ao paciente ou ao sistema de saúde.

3.4. Poder

O poder formal do *ombudsman* é bastante limitado. Ele não toma decisões restritivas; mas, faz relatórios e estes *"não são mandatórios"*, segundo a subseção dois do § 8-7. Eles terão o peso que as equipes de saúde lhe atribuírem e isso depende do impacto real desses documentos, o quão convincentes eles são em termos de conteúdo e argumentação. Sua credibilidade é construída pelo *ombudsman* por meio de investigações prévias.

Se o hospital não concorda com a avaliação do *ombudsman* em uma questão legal, o caso deve ser encaminhado ao Comitê Nacional de Vigilância em Saúde que tomará uma decisão. Na prática, muitas vezes, chega-se a um acordo com o hospital.

Freqüentemente, o *ombudsman* envolve-se em casos de riscos ligados ao tratamento hospitalar. Nestas situações, ele deve solicitar informações para esclarecer o caso e a instituição é obrigada a responder a estes pedidos e a enviar uma cópia de seus registros. Após analisar o caso, o *ombudsman* pode colocar o paciente em contato com o sistema de indenizações.

3.5. Discussão

Os principais objetivos do *ombudsman* são o de proteger os direitos legais e interesses dos pacientes e contribuir para a melhoria da qualidade do serviço de saúde. Como os interesses dos pacientes estão bastante concentrados no Ato dos Direitos dos Pacientes, o papel do *ombudsman* deve ter como foco avaliar como estes direitos são atendidos. A segunda função é uma derivação da primeira e implica em que o *ombudsman* utilize a experiência dos casos individuais para dar retorno ao sistema hospitalar. As informações fornecidas por este profissional devem, assim, ser um fator de melhora da qualidade dos hospitais.

A legislação não concedeu ao *ombudsman* do paciente o mesmo nível formal de autoridade do *ombudsman* civil. Não há uma predeterminação de que as instituições que prestam serviços de saúde devam cumprir o conteúdo dos relatórios do *ombudsman* e, desse modo, ele deve ser mais

reservado ao divulgar suas afirmações e atuar muito mais como um intermediário. Porém, o *ombudsman* pode propor uma ação legal, sugerindo aos pacientes que procurem assistência legal, ou encaminhando os casos para a autoridade pública de saúde ou para o Sistema de Compensação de Pacientes.

A função do *ombudsman* é limitada à atenção secundária da saúde. A Assembléia não apresentou nenhuma razão explícita para esta limitação, que não foi debatida extensivamente. Contudo, recentemente um grupo de parlamentares apresentou ao ministro da Saúde um pedido de discussão sobre o tema. O governo parece querer debater a inclusão da assistência primária no campo de trabalho do *ombudsman*, em 2008. Como mostraremos a seguir, há boas razões para isso.

4. ESTUDO DE CASO — A LEI

4.1. O direito de acesso ao ombudsman

De acordo com o Ato dos Direitos dos Pacientes, todos têm o direito de ter acesso ao *ombudsman*, como se vê no § 8-3(2): *"Qualquer pessoa pode procurar o* ombudsman *do paciente e requerer que seu caso seja analisado."* Esta cláusula inclui dois pontos importantes. Além dos pacientes, qualquer outro cidadão pode ter acesso aos serviços do *ombudsman*. E a requisição não é denominada de queixa; somente como solicitação é que ela deve ser encaminhada.

Além disso, as equipes de saúde podem contar com o *ombudsman* para a investigação de casos. Todavia, se eles estiverem relacionados a um paciente particular, somente este doente pode decidir se o *ombudsman* deverá ser envolvido ou não.

As requisições podem ser encaminhadas oralmente ou por escrito, o que faz parte do conceito de facilitar o acesso ao *ombudsman*.

O *ombudsman* também pode iniciar um caso por iniciativa própria e essa possibilidade é parte de seu dever em averiguar continuamente o sistema secundário de saúde.

4.2. O direito à confidencialidade

"Pessoas que procuram o ombudsman *do paciente são denominadas como anônimas"*, conforme o § 8-3(2). Isso significa que o *ombudsman* não deve solicitar aos cidadãos que lhe forneçam informações sobre sua identidade se eles não quiserem fazê-lo. Na prática, profissionais da saúde, de forma anônima, dão informações, por exemplo, sobre uma ação

considerada prejudicial a um paciente ou a um grupo de pacientes. O *ombudsman* deve respeitar o anonimato mas; isso causa mais dificuldades para as investigações. No entanto, normalmente, os pacientes revelam suas identidades.

4.3. Direcionamento das requisições

O *ombudsman* decide o que deve ser feito com os casos apresentados, como prevê o § 8-4: *"O* ombudsman *do paciente deve determinar, por conta própria, se uma solicitação apresenta conteúdo o suficiente para ser avaliada."* Isso depende das prioridades do *ombudsman* com relação ao caso. Porém, presume-se que ele se responsabilize pelos casos apresentados. Caso a requisição não seja considerada, o § 8-4 afirma que *"o solicitante deve ser notificado e deve ser dada uma explicação para a decisão"*. A explicação deve ser feita por escrito.

Uma razão para o *ombudsman* não encampar um caso é sua avaliação de que o pedido é relativo a uma área do sistema de saúde que não é de sua alçada.

Os profissionais e as instituições de saúde devem atender aos pedidos de informação do *ombudsman*, como prevê o § 8-5: *"Autoridades públicas e outros órgãos que prestam serviços à administração pública devem fornecer ao* ombudsman *todas as informações solicitadas para que ele possa desenvolver suas atividades."* Isso significa que, não apenas os profissionais dos serviços secundários de saúde, mas, todos os demais, incluindo um médico do serviço primário, devem fornecer ao *ombudsman* os dados dos quais ele necessita. Estas solicitações podem ser sobre tratamentos ou comunicação e há poucas limitações para esse direito, sendo que os artigos no Código Processual § 204-209 (sobre confidencialidade) são válidos para o *ombudsman*.

Ao investigar um caso, o *ombudsman* deve ter acesso às salas onde os serviços são prestados. Enquanto o direito de solicitar informações se aplica a todos os profissionais, o acesso aos locais onde são prestados os serviços de saúde se restringe ao atendimento secundário. Esta limitação não representa na prática qualquer problema.

4.4. Encerramento dos casos

A legislação não trata sobre a necessidade de se finalizar uma requisição. O *ombudsman* não é obrigado a fazer nenhum relatório, pelo fato de que este profissional atua de uma maneira informal. Muitos casos, assim, são encerrados com uma orientação ou conselho.

As decisões podem ser feitas de várias maneiras. Em muitos casos, não cabe ao *ombudsman* elaborar um relatório — a expectativa é a de que

ele encaminhe os casos. Se, por exemplo, o *ombudsman* considera que um serviço de saúde não está respeitando a lei, ele deve comunicar o Comitê de Vigilância em Saúde do condado, órgão que tem o poder de julgar a matéria. O solicitante, no entanto, tem o direito à informação sobre o andamento de seu caso e seus resultados.

4.5. Publicidade e relatório periódico

O *ombudsman* tem o dever de divulgar seu trabalho e a imprensa, freqüentemente, publica artigos sobre casos em andamento. Essa divulgação colabora para que o profissional seja conhecido pelo grande público.

Ao final do ano, o *ombudsman* publica um relatório apresentando suas atividades e resultados obtidos. Estes documentos são abertos ao público e é comum que a mídia os divulgue também.

Desde 2006, os casos individuais passaram a ser parcialmente coletados e registrados em um banco de dados.

4.6. Discussão

O acesso dos pacientes ao *ombudsman* é fácil, bastando fazer uma solicitação oral. Por outro lado, é o *ombudsman* quem determina se a solicitação é consistente e merece ser investigada. Assim, ele tem um bom controle sobre os casos que lhe chegam.

Para cada caso, o profissional avalia o encaminhamento mais apropriado a ser feito. A compreensão de sua função e de suas competências reais vai influenciar suas decisões e os resultados para os pacientes. Se o *ombudsman* vê a si próprio como um advogado ou como um "conselheiro espiritual", essa percepção terá um impacto significativo na condução do caso.

Se o paciente sente-se insatisfeito com o trabalho do *ombudsman*, ele pode apelar para o *ombudsman* civil. Na prática, situações como esta ainda não foram registradas, o que mostra que os cidadãos estão de acordo com o funcionamento do sistema.

5. ESTUDO DE CASO — A PRÁTICA[10]

6. ANÁLISE

As queixas dos pacientes podem ser submetidas à instituição de saúde que prestou os serviços (municípios, prestadoras de serviços médicos e

(10) Nota do editor: por razões editoriais, a versão em Português deste artigo não traz a tradução do item 5. Estudo de caso — a prática. Porém, o referido trecho pode ser consultado na versão original.

hospitalares). Se os pacientes acreditam que seus direitos legais foram violados, eles também podem encaminhar suas reclamações para o Comitê Nacional de Vigilância em Saúde, órgão competente para avaliar as decisões médicas e também para disciplinar as instituições e os profissionais da saúde. Caso considere o direito de indenização, eles devem encaminhar o pedido para o Sistema de Compensação dos Pacientes. E, na necessidade de ajuda exterior para ter seus interesses e direitos legais respeitados ou para apresentar seus casos ao Comitê Nacional de Vigilância em Saúde, ou outros órgãos públicos, os pacientes podem contar com o trabalho do *ombudsman*.

O *ombudsman* do paciente é uma figura de importância nas comunidades locais; ele contou com a boa reputação estabelecida com o *ombudsman* civil para chegar a esta posição. Geralmente, ele é bem aceito pelos administradores de hospitais, médicos e enfermeiros e os problemas por ele apresentados, normalmente, são solucionados em nível local; raramente necessitam de encaminhamento para a justiça. Porém, ainda se constitui em um desafio para o *ombudsman* apresentar casos para as autoridades de vigilância.

Até o momento, foram apresentados elementos que, em 15 anos de funcionamento do sistema de *ombudsman* do paciente, mostraram-se necessários para o esquema. Porém, existem questões que ainda não foram bem resolvidas: o campo de trabalho tem como foco apenas os casos do sistema secundário de saúde e o *ombudsman* ainda não conta com uma regulação que lhe confira treinamento *legal*.

Pesquisas com os *ombudsmen* mostram que eles vêem seu papel de maneiras diferentes. Alguns se enxergam como advogados; outros como intermediários ou conselheiros espirituais e há quem faça uma combinação de todos esses papéis. Essas variadas visões podem ser resultados de tradições locais dos condados ou da capacitação pessoal do *ombudsman* e devem ser melhor investigadas.

O papel do *ombudsman* do paciente deve ser desenvolvido, principalmente porque estes profissionais realizam seu trabalho de acordo com uma legislação comum a todos. Faz-se necessário algum tipo de organização ou fórum para ajudá-los a estruturar melhor sua forma de atuação. A população deve esperar que o *ombudsman*, em geral, dê os mesmos encaminhamentos para casos semelhantes. Algumas atribuições são comuns atualmente; mas, existem profissionais que, de acordo com os relatórios anuais, terão que modificar sua prática para se alinhar com determinados padrões de ação. Algo como:

> O *ombudsman* deve, em primeiro lugar, agir para ajudar os pacientes, quando eles necessitam de um apoio informal e para assegurar que os fornecedores relevantes de serviços de saúde prestem atenção às demandas dos cidadãos. Aparentemente, os *ombudsmen* agem dessa maneira.

Se o paciente ficar insatisfeito com a resposta dada pelo prestador do serviço ou se este prestador não tomar nenhuma atitude quanto à queixa, o *ombudsman* poderá encaminhar a questão de forma oral ou por escrito e levantar mais informações. Neste ponto, os *ombudsmen* não têm um comportamento padrão, sendo que alguns são mais ativos do que outros.

Se o *ombudsman* acredita que o prestador de serviço está infringindo a lei, isto deve ficar explícito. Em última instância, ele pode ajudar o paciente a encaminhar sua queixa ao Comitê Nacional de Vigilância em Saúde. Esta é outra atividade para a qual os *ombudsmen* adotam procedimentos diferentes entre si.

Se o prestador de serviço não pretende tomar nenhuma atitude quanto a um caso de potencial prejuízo ao paciente, o *ombudsman* deve solicitar a este mais informações sobre o eventual perigo e, além disso, solicitar uma cópia dos registros médicos. Esta atitude também deve colaborar para uma eventual requisição de indenização por parte do paciente. De acordo com as estatísticas, os *ombudsmen* também parecem ter diferentes formas de agir.

Problemas repetidos devem ser trazidos ao sistema hospitalar como uma preocupação com relação à qualidade dos serviços, de uma maneira mais geral. Em última instância, o Comitê Nacional de Vigilância em Saúde é o local para esse apontamento. Aqui também, existem variadas formas de ação por parte dos *ombudsmen*.

Dentro das comunidades, o foco do trabalho do *ombudsman* é questionado: este profissional deve agir como "advogado ou como uma ponte"? Estes são, no entanto, dois lados da mesma moeda: trata-se de um modo de ação formal ou informal. A resposta não é um "sim ou não". O foco deve estar, em primeiro lugar, no encaminhamento informal e, em caso de necessidade, o passo formal deve ser dado.

É uma dificuldade constante para o *ombudsman* encontrar soluções aceitáveis para todos. Atuar como uma ponte pressupõe, não apenas atitudes específicas, como também talentos pessoais. Pessoas com habilidade para ouvir o outro, comunicar e conciliar são importantes. E o *ombudsman* precisa também de conhecimento legal e capacitação para possibilitar que ele atue como um negociador.

Pouco a pouco, a Noruega introduziu uma nova legislação que deu aos pacientes mais direitos. Ainda não foram avaliados os impactos destas leis na instituição do *ombudsman* do paciente. Entretanto, espera-se que este profissional exerça mais do que um papel em matérias legais, conforme os pacientes sejam estimulados a exigir mais seus direitos. Ele também terá que atuar como uma ponte. Porém, quando este caminho falhar ou não for apropriado, o *ombudsman* deverá agir mais como um advogado, discutindo a questão ou encaminhando a queixa para os fóruns públicos.

Além disso, o *ombudsman* deve reunir informações, a partir dos casos individuais, que podem ser de grande interesse para o sistema hospitalar. É importante que ele identifique os problemas e procure assegurar que os prestadores de serviços de saúde tomem iniciativas para resolvê-los. É recomendável que, com base em sua experiência, individualmente ou em conjunto com a administração hospitalar, proponha e participe de estudos para investigar e entender os problemas e identificar medidas para solucioná-los.

O conhecimento e a informação de que dispõe o *ombudsman* do paciente são altamente relevantes na educação e este profissional pode compartilhá-los com as equipes das instituições de saúde, destacando sua importância para a proteção dos direitos dos pacientes.

Embora o sistema de *ombudsman* de pacientes esteja em funcionamento há 20 anos na Noruega, sendo os últimos sete anos com o Ato dos Direitos dos Pacientes, não há ainda uma análise que possa comparar o que tem dado resultados ou não na instituição. Apenas pequenas avaliações foram realizadas até o momento. Para o desenvolvimento desta instituição, é preciso realizar uma grande avaliação, verificando as formas de trabalho dos *ombudsmen* e a visão que os pacientes e os profissionais do sistema de saúde têm desta função.

7. CONCLUSÕES

Com base nas experiências de diferentes países europeus, foram elaboradas recomendações sobre como organizar um sistema de *ombudsman* de pacientes[11]. De acordo com estes conselhos, o sistema norueguês parece ser melhor desenvolvido, pois preenche muitos dos elementos necessários para a construção de uma estrutura bem ajustada aos seus propósitos: ser regulado por lei e manter um profissional trabalhando integralmente, de forma autônoma na investigação dos casos, com acesso ilimitado aos registros dos pacientes e o benefício de ver divulgados seus relatórios.

Ainda em comparação com outras nações da Europa, o sistema norueguês parece ter alcançado um degrau mais alto no que concerne a solucionar as queixas de forma a obter os resultados mais satisfatórios para os pacientes.

A partir desta experiência da Noruega, sugerem-se a seguir as seguintes recomendações para construção de um sistema de *ombudsman* de pacientes efetivo:

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(11) FALLBERG, L.; MACKENNEY, S. *Op. cit.*, p. 343-357.

a) O papel do *ombudsman* deve ser claro e suficientemente divulgado para a sociedade.

b) O *ombudsman* deve ser um profissional.

c) O *ombudsman* deve trabalhar de maneira independente.

d) O trabalho do *ombudsman* deve ser de dedicação exclusiva.

e) O *ombudsman* deve ajudar os pacientes a avaliarem seus próprios direitos.

f) Inicialmente, o *ombudsman* deve trabalhar de maneira informal.

g) O *ombudsman* tem que ter autoridade para investigar casos.

h) O *ombudsman* tem que ter acesso a documentos relevantes.

i) O *ombudsman* tem que, se necessário, usar o sistema formal para assistir os pacientes.

j) Deve-se esclarecer (por escrito) porque determinado caso não foi aceito.

k) As atividades do *ombudsman* devem ser divulgadas para a sociedade.

l) Os *ombudsmen* devem cooperar entre si e ter um fórum de discussão em constante funcionamento.

m) As informações e experiências das atividades dos *ombudsmen* devem ser reunidas e eles devem compartilhá-las com os serviços de saúde, com o propósito de contribuir com a melhoria do sistema de saúde.

n) O sistema tem que estar regulado por lei.

o) O financiamento do sistema tem que ser público.

p) O acesso ao sistema tem que ser gratuito.

q) A estrutura do sistema deve ser organizada localmente.

r) O profissional deve ter competência nas áreas do Direito e da Saúde.

s) O sistema deve contar com publicidade.

t) O sistema tem que ser regularmente avaliado.

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VERSÃO EM INGLÊS

THE PATIENT OMBUDSMAN — THE NORWEGIAN EXPERIENCE

Olav Molven (*)

1. BACKGROUND AND FRAMEWORK(1)

1.1. Introduction

The word "Ombudsman", originally a Scandinavian word introduced some three hundred years ago, is used to identify someone who has both the right and the power to speak on behalf of someone else. Many countries have depending on their own traditions and values, developed such administrative systems with different rights and powers to protect the individual citizen against (parts of) he public sector body.

The Norwegian Ministry of Social Affairs discussed in a report to the Parliament in 1975 whether patients in social- and health institutions should have a special Ombudsman to whom they could present their complaints. No action was taken at that time. From the middle of the 1980s, however, the 19 counties in Norway started on their own to establish arrangements called Patient Ombudsmen to especially support patients. In 1999 the Act on Patients Rights was enacted, and the Patient Ombudsmen from then have their legal basis in that law.

To understand the rights and the powers of the Patient Ombudsmen in Norway (the Norwegian Patient Ombudsman scheme) requires some contextual knowledge about the framework the Ombudsmen are working within. This paper therefore starts with a description of the Norwegian health care system, the health legislation, and some of the most relevant arrangements regarding health services. The Patient Ombudsmen's functions are also seen in the light of the Parliamentary Ombudsman.

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(1) This article is mainly based on to earlier articles; MOLVEN, O. *The patient Ombudsman Scheme*: a contribution to legal safeguards and quality in health service. *Norwegian Law Journal*, 1991 (in Norwegian), and especially on MOLVEN, O. The Norwegian Patient Ombudsman Scheme. In: MACKENNEY, S. *Protecting patients rights? A comprehensive study of the ombudsman in health care*. London: Radcliffe Medical Press, London, 2004 by Radcliffe Medical Press, London.

1.2. The health care system

Norway has about 4,5 million inhabitants, and is divided into 19 counties with population ranging from about 75.000 to 500.000. The counties are further divided into municipalities of which there are 434. Democratically elected Boards govern both the counties and the municipalities. The national state authorities control overall policy design and the capacity and quality of health care through budgeting and legislation. Norway is in many ways an egalitarian country: The state finances a National Insurance scheme that covers each citizen in a uniform way, all residents are entitled to the same services, and the services must legally be provided to a minimum standard. This is a part of the national welfare state program that has been carried out the last 50 years.

The municipalities are responsible for primary care. This includes general practitioners, midwifery, a central emergency call-line, home nursing care, nursing homes, physiotherapy and both individual and environmental preventive health care. Recently, a population based fixed list system for general practitioners, was implemented. The state is responsible for secondary (specialised) health care including somatic and psychiatric hospitals, this function being delegated to four regional state-owned health care enterprises, each with their own board. Counties are responsible only for dental services, especially for children, the elderly and people with disabilities.

Some of the general practitioners are employees within the municipalities and the rest work on a contractual basis with the municipalities. Nearly all hospitals are state owned and run, and the physicians and other health personnel are employees. Most of the few private hospitals work on a contractual basis with the health care enterprises. Also most specialists outside the hospitals work on such a basis with these enterprises. Thus pure private services represent a very small part of the health care services.

1.3. Health legislation

All laws are enacted by state Parliament. In practice they go a long way towards regulating specific issues. The national government or a ministry is given authority to issue more detailed regulations on topics if explicitly specified in written law. Such regulations supplement statutes, especially on technical matters, but play a rather minor role in Norwegian health law.

The legislation has in principle been organised in five areas that regulate respectively:

— the financing of health services;

— the relevant administrative bodies responsible for health services, and of the minimum range of services to be provided;

— the relationship between these institutions/bodies and health care staff employed by them;

— the relationship between citizens/patients and these institutions/bodies;

— the relationship patients and health care staff.

2001 saw significant reform of health legislation. An important part of this was to introduce a small number of comprehensive statutes. Each statute governs major elements of the health care system and its operation, and collectively they cover almost all aspects of health. It is perhaps fair to say that we now have nine main health laws:

— the Social Security Act;

— the Patients' Rights Act;

— the Municipal Health Services Act;

— the Specialised Health Services Act;

— the Mental Health Care Act;

— the Health Care Personnel Act;

— the Act on Communicable Diseases;

— the Supervision Act;

— the Act on Patient Compensation.

1.4. Patients' rights[2]

Legislation has increasingly been built up in accordance with the principle of rights and duties to safeguard patients' interests[3]. Citizens and patients have the rights. Those who have duties corresponding to these rights are mainly the municipalities, the state and the different (groups of) health personnel. Therefore, what is described as a right in the Act on patients' rights is correspondingly described as a duty in the acts relating to municipal health services, secondary health services and/or health personnel. Though some rights may be considered vague, many are very specific. The right-duty system also gives rise to the fact that patients who consider their rights have been infringed may have their cases tried by the Norwegian Board of Supervision or by the court (see below).

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(2) KJØNSTAD, A. The development of patients' rights in Norway. In: MOLVEN, O. (Ed). *The Norwegian Health Care system*: legal and organizational aspects. Oslo: University of Oslo, 1999. p. 125-140.
(3) MOLVEN, O. The guiding principles of Norwegian Health legislation. In: MOLVEN, O. (Ed). Health *Legislation in Norway*. Oslo: Ad Notam, 2002. p. 18-27.

The series of patients' rights are mainly set in the Act on Patients Rights. Basically, patients have the right to consultation and treatment, together with a free choice of physician and of hospital. It is stipulated as a duty both in the Health Care Personnel Act, the Municipal Health Services Act and the Specialised Health Services Act that services must be of a minimum standard: *i. e.* they must be of reasonable quality. Furthermore, patients do, for example have the right to participate in making treatment decisions, the right to informed consent to medical treatment, the right to access to medical records, the right to have a copy of their records, and the right to medical confidentiality. Importantly for the purposes of this paper, patients also have the right to complain when they think their rights have been violated.

From 2004 the citizens' rights to hospital treatment have been considerably strengthened. Hospitals can not use lack of capacity as a reason for not giving health services to patients that otherwise fulfil the criteria set by the law for having right to evaluation and treatment. The state-owned health enterprises have now, if they not can offer the patients treatment themselves, duty to provide specialised health services by sending such patients abroad, and the enterprises have then to pay for it.

1.5. The rule of law

To ensure that the laws and the rights are put into practice, certain measures have been designed:

Those who deliver health services have a legal obligation for to establish an internal control system. This means establishing systematic measures to ensure and document that activities are performed in accordance with requirements laid down by legislation or regulations. These systematic measures must be specified in administrative procedures.

A supervisory authority — an independent state board named The Norwegian Board of Health Supervision that also includes 18 agencies on county level — is responsible for overseeing health services and health workers. They determine whether health care providers have an internal control system, and whether services comply with law and regulation.

Patients who are of the opinion that their rights have not been met have, according to the Act on Patients' Rights § 7-1, the right to ask those with the corresponding duties of service to revisit their decisions. They, *e. g.* the hospitals, have a duty to give an answer.

Patients who believe his or her rights have been violated have also the right to complain to the Norwegian Board of Health Supervision in the Counties. This authority evaluate what has happened, and has also the power to reverse a decision made by the health service or by health personnel, and may ultimately institute disciplinary proceedings.

Patients who have suffered damage may present their case to the Norwegian System of Compensation to Patients. This is a public, neutral body, that do the claims' handling when patients are asking for economic compensation.

There are both a Parliamentary ombudsman and 19 local Patient Ombudsmen to safeguard patients who need assistance in securing their rights towards the health service, e.g. the hospitals. The Patient Ombudsmen also help patients to present their complaints to the Board of Health Supervision in the Counties and the System of Compensation to Patients. Before discussing the Patient Ombudsmen scheme, I will give a brief overview over the role of the supervisory authority, the Patient Compensation Scheme and the Civil Ombudsman.

1.6. The supervisory authority[4]

The Norwegian Board of Health Supervision on central level lead by a Director General is the co-ordinating unity of the supervisory authority. This is a professional agency under the Ministry of Health and Care Services. For technical matters, this board is an independent body, and the Ministry cannot instruct or overrule the board in their handling of cases. The Norwegian Board of Health Supervision in the Counties, lead by this central unit, carries out the external supervision of health services and health care personnel. The Board of Health Supervision in the Counties is lead by county medical officers. The staffs consist mainly of different kind of health personnel and lawyers.

The patients have the right to have virtually all decisions made by the health service or health personnel, concerning rights to health services, information, consent and disclosure of documentation, reviewed by the Norwegian Board of Health Supervision. The law on patients' rights § 7-2 states:

> "*If the health care provider rejects the request, or if he is of the opinion that the rights has already been performed, a complaint may be submitted to the county medical officer. The complaint shall be sent to the Norwegian Board of Health Supervision in the county.*"

The Norwegian Board of Health Supervision in the Counties has both the power and the duty to reverse any decision that is not in accordance with the law. Decisions made by the supervisory authority may be brought to the court.

Patients have also a right to have cases tried even where there is no specific action to reverse. The Norwegian Board of Health Supervision in the Counties must always consider the patients' views when such cases are brought before them, and determine whether the law or regulations have been broken. As stated in the law on health personnel § 55:

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(4) Disponível em: <http://www.helsetilsynet.no/templates/sectionpage____5499.aspx>.

"A person, who is of the opinion that provisions relating to duties stipulated in or pursuant to this Act have been breached in his disfavour, may request an assessment of the matter from the supervising authority. The patient may act through a representative. The request is to be sent to the Norwegian Board of Health Supervision in the counties.

The Norwegian Board of Health Supervision in the counties shall consider the views put forward in the request, and may also address other matters than those put forward in the request."

Closing the case, the Norwegian Board of Health Supervision in the Counties must provide a decision where it is stated whether the law has been broken or not, and if necessary they should give guidance to health personnel and/or the health service.

The Norwegian Board of Health Supervision is responsible for co-ordinating the whole supervisory authority so their application of the law is uniform throughout the country. If county officers are of the opinion that health personnel have negligently contravened duties in the Act on Health Personnel, and the breach of this duty is liable to endanger the safety of health services or impose a considerable burden on patients, they have a duty to report to the central body. The National Board of Health Supervision has the power in such cases to give the relevant health personnel a warning and in very serious cases even withdraw their licence to practise[5], and to instruct the health service to change their practice.

1.7. The Norwegian System of Compensation to Patients[6]

This compensation scheme covers all patients receiving any form of health care from any public health service and private service working on a contractual basis with the public service. The scheme includes patients receiving health care from for example doctors, nurses, midwives, dentists, physiotherapists, pharmacies, orthopaedic practitioners, and in ambulances. From 2008 all patients receiving health care from private service also will be covered by this scheme.

The principal element of the law is to determine whether or not a hospital or medical professional has failed in its duty when a patient has suffered damage, even if no one is at fault. There are also circumstances set out in the law which establish liability where there has been no failure; in specific situations there is strict liability. This means we should perhaps characterise the scheme as an arrangement somewhere between a no-fault and a malpractice system.

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(5) MOLVEN, O. Reactions against health personnel that are not complying with the law. In MOLVEN, O. (Ed). *Health Legislation in Norway*. Oslo: Ad Notam, 2002. p. 124-136.
(6) JORSTAD, R. G. The Norwegian System of Compensation to Patients. *Medicine and Law*, v. 21, n. 4, p. 681-686, 2002.

To obtain compensation there must also be a proven causal connection between the incorrect treatment and/or diagnosis and the alleged injury. In some situations is it not necessary to *prove* a causal connection. For example is it stated in the Act on Patient Compensation § 3:

> *"If the cause of damage to a patient's health cannot be established and the damage is in all probability attributable to an external influence during the treatment of the patient, it shall be assumed that the damage is caused by fault or failure in the providing of health services."*

Patients who are not satisfied with the decision made by the System of Compensation to Patients, may appeal to a special board, and may ultimately have the case tried in court. In practice around 10 % of the cases are brought before this special board, and only about 1 % before the court.

1.8. The Civil Ombudsman

The Parliament's Ombudsman for Public Administration (hereafter named Civil Ombudsman) was in place as early as in 1962. Public administration had already then become a huge body within the framework of the welfare state. Most citizens had to deal in many ways with this public administration, and felt often powerless as individuals in the face of such a large organisation. Though citizens in Norway traditionally think public authorities act on behalf of them, and to a high degree, at least compared with many other countries have confidence in them, it was seen necessary to give the citizens possibility in an easy way also to control these authorities. An independent body was needed to carry out an investigation without having to resort to protracted court battles. The system with the Civil Ombudsman was established. The Parliament elects this Ombudsman, who is accountable to Parliament.

The task of the Civil Ombudsman is to ensure that injustice is not committed against the individual by the public administration, by civil servants or by other persons working within the service of the public administration. The intervention of the Civil Ombudsman follows a complaint or can be on his own initiative. Any person who believes he or she has been subject to injustice by the public administration has the right to bring a complaint to the Ombudsman. Likewise any person who has been deprived of his or her personal freedom is entitled to complain to this Ombudsman. At the end of the case handling the Civil Ombudsman must provide a decision where he gives his opinion on the issues relating to the case. When the Ombudsman expresses a point of view, the public authority in practice responds to this.

In the middle of the 1980's the complaints concerning health care services represented less than 50 cases (less than 2% of all cases) reviewed by the Civil Ombudsman. Taking into consideration the importance of the health

service within public administration as a whole, the Ombudsman therefore played a relatively minor role in securing the rule of law for patients. This figures has not changed much since that time, however, then the system with the Patient Ombudsman was established, and the Patient Ombudsman after a short time got many cases related to health care provision.

1.9. The Patient Ombudsman

Patients' rights developed during the 1980s to be a central concept within Norwegian legal research, public debate, health administration and the administration of justice. The concept of patients' rights had particularly positive connotations, and was accorded considerable weight in health politics. A part of this development was that most of the counties during the second part of the 1980s and the 1990s established Patient Ombudsman schemes. This meant that the 19 counties, which at this time were responsible for secondary health care, including all hospitals, on a "volunteer" basis set up Ombudsman schemes that had secondary health services as their function.

Through county directives the Patient Ombudsmen were afforded a relatively free professional position. They could not in specific cases be influenced by for example the county administration or hospital directors. At the end of the 1990s the Patient Ombudsman received about 5000 requests every year. In the county and municipality of the capital Oslo, a special ombudsman scheme was arranged. In addition to secondary health services, this scheme also included primary health care and social services.

Within this more or less informal framework Patient Ombudsman schemes in the different counties tended to differ in some ways. Some of the Ombudsmen took on the role of "reporter", "spokesman" or even "lawyer"; some acted as "intermediaries"; some more like a "spiritual adviser"; and others again acted as "jacks-of-all-trades"!

During the late 1980s and the 1990s a number of the Patient Ombudsmen schemes were evaluated. Some articles related to this new institution were also published. In one of these the following opinion on the future of the system, based on experiences documented until that time, was set out[7]:

> "The aim with the Patient Ombudsman must be to safeguard the patients' interest and legal rights and be a suitable measure to improve the quality of the health care services. ... The scheme must in the future (also);
>
> — be regulated by law;
>
> — have health services as a whole as their function;

(7) MOLVEN, O. The Patient Ombudsman Scheme — A Contribution to Legal Safeguards and Quality in the Health Service? *Lov og Rett (Norwegian Law Journal)*, p. 195-222, 1991. (Only in Norwegian)

— be free of charge;

— organised regionally;

— carry out the work independently;

— have legal competence."

All counties had their own Patient Ombudsman at the end of the 1990s. From 2001 the Patient Ombudsman institution got its legal basis in the Act on Patients' Rights and is statutory in each county. Today the Patient Ombudsmen receives about 11000 requests a year. In the following this Patient Ombudsman system will be examined. The term Patient Ombudsman will be used both referring to the institution itself and to the staff at each office. The context of the text will clarify if it is the institution or the staff that is being referred to.

2. THE ORGANISATIONAL STRUCTURE

2.1. Legal basis

In the Act on Patients' Rights chapter 8 the purpose, scope and powers of the Patients' Ombudsmen are outlined. The scheme is described more in detail in the Proposition presented by the Ministry to Parliament (Odelsting)[8] and in the Recommendation from the health committee to Parliament[9]. The Ministry of Health and Care Services is empowered to issue regulations, however, such regulations have not yet been provided.

2.2. Level of functions

*The Patient Ombudsman was as mentioned originally established on a regional level in each of the counties. From 2002 the 19 Patient Ombudsmen have become a national institution. The government is responsible for ensuring, according to § 8-2, that; "*Every county municipality shall have a patient ombud*". The Patient Ombudsman therefore has a county as his territory. People who either live in the county or get their health care there may use the Ombudsman located in that particular county.*

The Patient Ombudsman and the Civil Ombudsman functions different levels. The Civil Ombudsman functions under Parliament, is located in the

(8) Proposition n. 12 (1998-99) to the Odelsting (Parliament). About the Act on Patients' Rights, chapter 8. (Only in Norwegian)
(9) Recommandation nr. 91 (1998-99) to the Odelsting (Parliament). The Act on Patients' Rights. (Only in Norwegian)

capital, Oslo, and has the whole country as his area. The 19 Patient Ombudsmen functions under the Ministry of Health, are located in each of the 19 counties, and have their attention focused on health services and the local population.

2.3. Localisation and staffing

The Patient Ombudsmen usually have their office located in one of the larger cities in the county, often where the largest hospital is situated. Some of the Ombudsmen also have an office at the biggest hospital, and make visits to the other hospitals in the area.

The Ombudsmen has no other functions in addition to the being an Ombudsman. He may therefore concentrate only on the tasks attached to this position. This avoids conflicts of interest. In the smallest counties the Patient Ombudsman is a single individual. In most counties there is in addition one or two staff. In Oslo, the biggest office, there is about 10 staff. This is due to they, as opposed to the others, also have primary health care and social service as part of their responsibilities.

Usually the Patient Ombudsman is a lawyer. Some are health personnel that in addition have legal training. For example are some both nurses and lawyers. It is common that the staff in bigger Ombudsman offices collectively have both legal and health competence.

2.4. Funding arrangements

The Patient Ombudsman is funded publicly from the state. The state decides also how many staff the Ombudsman needs in addition to himself. There is no fixed norm for this. In practice the state has taken over employment of the staff that were originally appointed in each county. The Patient Ombudsman is intended as a free service for every citizen and does not levy charges.

2.5. Regulation and accountability

The Ombudsman shall discharge his duties autonomously and independently of the Ministry and other public institutions. In § 8-2 it is stated; "The ombud shall carry out his work independently". Parliament emphasised this in their comments on the provision. So it is quite clear that no one can affect the Ombudsman in individual cases. And practice has shown that the Ministry has not tried to influence the Ombudsmen.

Regulations and guidelines may be issued by the Ministry. § 8-8 states; "The Ministry may issue regulations on the implementation of the provisions

relating to the patient ombud and may also issue supplements to these provisions". This must be seen in light of § 8-2. Guidelines may then only regard organisational and administrative questions, such as staffing and training demands, not decision making in cases.

2.6. Discussion

The organisational structure is in many ways fixed. There is a legal basis for the scheme, there is clarity about the level of functions, the funding arrangements are clear, and there is no doubt that the ombudsman works independently. There may however be a challenge to the independence of the Patient Ombudsman in that the system is organised under the Ministry of Health and Care Services, especially as this body in the end also is responsible for and organises the delivery of secondary health care. However, since it is so clearly stipulated that the Ombudsman shall work independently, there is not reason to fear that public authorities will try to instruct him.

3. ROLE AND FUNCTIONS

3.1. Aims

The objective of the Patient Ombudsman scheme is, as stated in § 8-2, twofold: *"The patient ombud shall work to safeguard patients' rights, interests and legal rights in their relations with the health service and to improve the quality of the health service."* The Ombudsman is consequently regarded as an important institution both in applying the rule of law in the health service and to improving quality of health care.

The Patient Ombudsman shall, according to the Parliament, act in different ways to achieve these aims. The Ombudsman should pursue cases following complaints from patients/citizens. On his own initiative he should also pursue cases that in other ways come to his knowledge, and should be pro-active in seeking such intelligence. It is expected that the Patient Ombudsman shall feed this knowledge back to the health service.

As to legal rights, the Ombudsman should be an intermediary for complaints to the right instances. The Ombudsman determines together with the patient to whom their complaints should be directed, for example to the National Board of Health Supervision or the System of Compensation to Patients for deciding on cases that are relevant to them.

The Ombudsman shall according to § 8-1, work with patients' needs and interests on a more general basis as well as working with "legal

rights"[10]. He focus should be both on the individual patient and patients as a group. In terms of needs and interests, it is said that the Ombudsman should make contact and communicate with the health service to feed back what patients have experienced and what they think, and thus also seek to avert more formal conflict.

3.2. Functions

At the time being the functions of the Patient Ombudsman involve, according to § 8-2, public secondary health care and only this. The Ombudsman shall not deal with primary health care and private specialist health service. Patients that are not satisfied with these elements of health service may, however, get information from the Ombudsman about the right way to direct such complaints. Usually the Board of Health Supervision in the County is appropriate for such complaints as there is no general informal route for dealing with such cases.

The Act on Patients' Rights, the Act on Specialist Health Service, the Act on Mental Health Care and the Act on Health Personnel are laws that are relevant in terms of secondary health care. The Ombudsman will therefore commonly in legal matters have to deal with cases relating to these laws. The question is regularly on the one side whether patients' rights have been violated and on the other side whether the health service and/or health staff have fulfilled their duties. The question in some cases is also whether patients are entitled to compensation under the Act on Patient Compensation.

3.3. Tasks

The main task for the Ombudsman is to give information, advice and guidance. When a patient asks the Patient Ombudsman for assistance, it follows from § 8-7(1) that *"To a reasonable extent, the patient ombud shall give anyone who requests it information advice and guidance in matters that are included in the work of the ombud"*. This means the central task involves giving patients information about rights and duties, and about the right place to go next. The assistance also includes, for example, supporting patients if they need to meet with health service staff. It also involves handling complaints either informally by asking the health service to perform their duties towards the patient, or more formally for example by asking the su-

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(10) About different Ombudsmens participation in ensuring patients' legal rights in different countries, see S SEGEST, E. The Ombudsman's involvment in ensuring patients' rights. *Medicine and Law*, v. 16, n. 3, p. 473-486, 1997 and FALLBERG, L.; MACKENNEY, S. Patient Ombudsman in seven European Countries: an Effective Way to Implement Patients' Rights? *Journal of Health Law*, v. 10, p. 343-357, 2003.

pervisory authority to reverse a decision and/or to discipline a member of staff or an institution. It is also explicitly stated in the preparatory work of the law that the Ombudsman may present suggestions for quality improvement and should also be actively involved by the hospitals in their work for achieving this.

The Patient Ombudsman has the right to make his opinion public. As stated in § 8-7 subsection two, *"The patient ombud is entitled to give his opinion on matters that are included in the work of the ombud, and to suggest concrete measures of improvement. The patient ombud himself shall decide whom these statements shall be directed to."* This power to give particulars and choose to whom this shall be given supports the Ombudsman's role as an important body in introducing solutions and improvements.

The Patient Ombudsman may give his opinion in cases relating to individual patients or groups. On the other side, he may not do anything against a patient's wishes. So if a patient for example does not want to make a complaint to the supervisory authority, the Ombudsman must respect this, even if it is obvious that the patient will win his or her case. The Ombudsman may, however, use the case anonymously if it is important from a general perspective to highlight the problems raised by the case. In some cases he have to report to the Board of Health Supervision (see below).

When cases are closed, the Ombudsman must inform the patients of the outcome, and give reasons for the outcome. As stated in § 8-8 subsection three *"The patient ombud shall notify anyone who has made a request to the ombud of the outcome following the handling of a case, and a brief explanation of the result"*. For example this explanation may include, depending on circumstances, forwarding a copy of the final report from the Ombudsman to the relevant health body, or a copy of the complaint sent to the National Board of Health Supervision. It may also include a copy of the hospital's final report to the Ombudsman about any complications in connection with treatment, linked to any conclusion by the Ombudsman that there is, or is no legal justification for claiming compensation.

The supervisory authority has in some situations to be informed by the Ombudsman. § 8-7 subsection four states; "The patient ombud shall notify the supervising authorities of conditions where a follow-up by the authorities is required." In practice the supervisory authority always follows up cases involving possible negligent breach of duty by the health service or health personnel, which have resulted in a considerable burden to the patient or represent a threat to the safety of health services. If the Patient Ombudsman is involved in such a situation, he therefore has a duty to report this to the National Board of Health Supervision regardless of the opinion of the patient involved.

3.4. Power

The formal power of the Patient Ombudsman is very limited. The Ombudsman does not make material decisions that are binding for others, only statements, and according to § 8-7 subsection two these statements *"are not mandatory"*. They have only the weight that health staff or service choose to give them. This depends very much on the real impact of the statements, how convincing they are in terms of substance and argument, and the general credibility the ombudsman has built up through previous investigations.

If the hospital does not share the same opinion as the Patient Ombudsman on a legal question the Ombudsman may according to § 8-7 bring the case to the supervisory authority for a legal binding decision. The National Board of Health Supervision in the Counties has the power to interpret the law and make such a decision. In practice the threat of action before this authority many times leads to an agreement with the hospital.

Frequently the Patient Ombudsman gets involved in cases about damage potentially linked to treatment in hospitals. In such cases the Ombudsman may ask for information to clarify the facts. Hospitals are obliged to answer these requests (see below), and to send a copy of the record. Having reviewed the case, the Ombudsman may bring the patient in contact with the System of Compensation to Patients if the patient wants to claim economic compensation.

3.5. Discussion

The main aims with the Patient Ombudsman schemes are to safeguard patients' interests and legal rights; and to contribute to the quality of the health services. As patients' interests now to a great extent concentrate on legal rights through the Act on Patient Rights, the Patient Ombudsman's role must be focused on how these legal rights are fulfilled. The second role is probably primarily to be seen as deriving from the first one. The Ombudsman should use the experience from the individual cases to put together reports back to the hospital. Accumulated data from the Ombudsman may thus be a factor in the hospitals' improvement of quality.

The legislature has not accorded the Patient Ombudsman the same level of formal authority as the Civil Ombudsman. It is therefore not predetermined that health service institutions will comply with statements from the Patient Ombudsman. This Ombudsman has consequently to be more reserved in issuing statements and more take the role as an intermediary in the case handling. However, the Ombudsman may take legal action by asking patients to seek legal assistance or by sending cases to the supervisory authority or to the System of Compensation to Patients.

The Patient Ombudsman's function is limited to secondary health care. Parliament has not provided any clear reasoning for this. This is a limitation that has not been debated extensively. A group within Parliament has, however, recently asked the ministry to present a paper discussing this matter, and the ministry seems now to have on the agenda to include the primary health care in the Ombudsman's field of work from 2008. As will be shown below, there are many good reasons for this.

4. Case-handling — the law

4.1. The right to contact the Patient Ombudsman

According to the Act on Patients' Rights everyone has the right to contact the Patient Ombudsman, see § 8-3(2): *"Anyone may contact the patient ombud and request that a case be handled."* This provision includes two important points. In addition to the patients, anyone else may contact the Ombudsman to have a case handled. And the requests are not named as complaints, only as requests that should be handled. This shall be done under the perspective of safeguarding patients' rights, interests and of improving the health services.

Also health services and health care staff may use the Patient Ombudsman to have cases investigated. However, if the case relates to a particular patient, only that patient can decide what involvement the Ombudsman should have.

As stated in § 8-3, handling may either be on the basis of an oral request or a written request. So it is not necessary to submit a written request to contact the Patient Ombudsman. This is a part of the concept that there should be a low-threshold to accessing support.

The Ombudsman may also initiate a case of his own accord. This is linked to the duty to scrutinise secondary health care services on an ongoing basis. In particular, the Ombudsman has to intervene if an activity appears to go beyond what may be regarded as sound professional practice.

4.2. The right to confidentiality

"Persons who contact the patient ombud are entitled to be anonymous", see § 8-3(2). This means that the Patient Ombudsman may not ask individuals giving information to disclose their identity if they don't want to. In practice, anonymous health personnel provide information, for example about an action, which they consider has been to the detriment of a patient or patients as a

group and should be remedied. The Ombudsman has to respect anonymity, but this may create more difficulties in investigating the case. Usually however the patients or other individuals who contact the Ombudsman reveal their identity.

4.3. Handling of the requests

The Patient Ombudsman decides himself what shall be done with the cases presented. As stated in § 8-4 *"The patient ombud shall by himself determine if a request provides adequate grounds for further handling"*. It will depend on the priorities of the Ombudsmen whether cases are followed up. It is presumed, however, that the Ombudsman normally will take the case. If the case is not handled, it is stated in § 8-4 that *"the person who made the request shall be notified thereof, and be given a brief explanation for this decision"*. According to good management, the explanation must be given in written form. One reason for not handling the case may be that the Ombudsman considers it to relate to a part of the health service that falls outside his functions.

The health personnel and hospitals have to give the Patient Ombudsman the information he is asking for. According to §8-5 *"Public authorities and other bodies that provide services for the public administration shall give the ombud the required information in order for the ombud to carry out his tasks"*. This means that any such authority shall give information; not only bodies within the secondary health care services. A doctor in primary care must likewise provide the Ombudsman with information requested. This information might be about treatment, communication, correspondence etc. There are few limitations to this right to demand information, though the provisions of the Civil Procedure Act §204-209 (about confidentiality) apply correspondingly to the Ombudsman.

Investigating a case, the Ombudsman shall as stated in § 8-6, have access to all rooms where public secondary health services are being provided. While the right to obtain information applies to all public authorities, the access to the premises applies only to secondary health care services. This limitation does not — at present — in practice represent any problem, as it is only, for the exception of the capital Oslo, the secondary health services that are part of the Ombudsman's field of work.

4.4. Bringing the cases to close

The law says nothing about bringing the cases to close. The Patient Ombudsman is not obliged then, as the Civil Ombudsman, to make any statement. This is linked to that the Patient Ombudsmen are expected to work in an informal way. Many cases thus end up with giving guidance or advice.

Decisions can take a number of forms. In many cases it is not suitable for the Ombudsmen to make statements — the expectation is often that the Ombudsmen instead set cases on the right decision-making track. If the Ombudsmen for example consider that a health service provider is not respecting the law in spite of what he has said, he may bring the case to the Board of Health Supervision in County who has the power to adjudicate the matter. The person that has asked the Ombudsman for support has, however, has the right to be informed about the result of the case handling, and be given a reason for the result.

4.5. Publicity and periodic reporting

The Patient Ombudsmen have according to § 8-7 the duty to publicise their own role and their way of acting. They achieve publicity in other ways also. Frequently the local newspapers have articles about the Ombudsman linked to special cases they have handled or more in general. In the long run this type of publicity has made the Ombudsmen well known.

Annual reports are also published at the end of the year about the activity and results. The reports are open to public review and it is common that the newspapers refer to these reports. In this way the Ombudsmen get publicity not only about the individual cases that patients wish to have aired, but about their activity in general. From 2006 individual cases have partly been registered in the same way and collected in a shared register. From this time we have some aggregated data from all the Ombudsmen.

4.6. Discussion

It is easy for patients to contact the Patient Ombudsman. They don't need to write a letter, it is enough to make an oral request. On the other hand, it is the Ombudsman who determines whether a request provides adequate grounds for further investigation. The Ombudsman therefore has a good deal of control over individual cases.

The law does only to some extent regulate the case-handling. Different courses of action may bee taken in the cases depending on what the Ombudsman considers appropriate. The role he sees himself playing, or the role he has real competence to play, may influence these decisions and then perhaps the results for the patients. Whether the Ombudsman sees himself on the one hand as a lawyer or on the other as a spiritual adviser may in individual cases have a significant impact on the handling of the case.

If the patient is dissatisfied with the work done by the Patient Ombudsman, he may appeal to the Civil Ombudsman. In practice such cases have yet to be raised. This may indicate that few patients are very dissatisfied with the

case handling. In the following the case handling in practice will be examined to see what kind of action is taken and what the patients think about the support they have got.

5. Case handling — the practice

5.1. Inquiries and cases

The Patient Ombudsmen have as mentioned above from 2001 operated under the Act on Patients Rights', and since 2002 they have administratively worked under the aegis of the state. In the year 2006 the Ombudsmen handled some 11000 requests. This represented an increase of 50% from year 2000, and 10 % from 2005. About half the requests were investigated.

Nearly 2000 of the requests dealt with the primary health care. These cases were not handled in reality, this means beyond giving advice, except for the county of Oslo where the Ombudsman also has primary health care as a part of his sphere of authority. And about half of the cases regarding health care providing that the Ombudsman in Oslo handles are linked to the primary health care.

There has not been any evaluation of the Patient Ombudsman Scheme following the changes from 2001 and 2002. However, in reality the legal authorisation and organisational restructuring has probably led to few changes in handling cases as the changes are more of formal art; *e. g.* the Act on Patients Rights to a great degree confirms earlier way of thinking of the Ombudsmen's roles. Observations and evaluations of practice in the 1990s will therefore probably to a great extent also be valid today.

In fact there has either in the 1990s been any common evaluation of the 19 different Patient Ombudsmen taken the starting point in the patients' and/or the health personnel's point of view by asking them. Therefore, to illustrate case handling in practice, the basis must be taken on basis of the figures from the evaluation of some of or one of the Ombudsmen.

For the purposes of this paper, the Patient Ombudsman selected is in the county of Nordland. This is in many ways an average Norwegian county, and the arrangement there has lasted for many years and it has been evaluated twice, most recently in 1997[11]. The Patient Ombudsman in this county receives about 750 enquiries a year from patients and others. The figures from Nordland will be supplemented by more general data from some of the other Ombudsmen.

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(11) HBO-Report 7/1997, ""Advocat or bridge builder". Evaluation of the Nordland Patient Ombudsman Scheme". (only in Norwegian).

308 patients were surveyed during the last evaluation that took place in Nordland. Of the 308 cases raised by them who took part in the evaluation, females brought up some 55%. People older than 50 raised some 50% of the cases. Patients themselves raised about 75% of cases, relatives approximately 20%, and others around 5% of the cases. This breakdown has remained largely the same for the last 10 years.

5.2. Availability

Of 308 patients surveyed during the evaluation, 92% answered that it had been easy to contact the Patient Ombudsman. Data from other counties confirms this. In contacting the Ombudsman, 50% in Nordland said that they used telephone, 20% that they wrote a letter, and 16% that they met the ombudsman while he was visiting the hospital. The remainder were unsure which method was used first.

5.3. Why do patients contact the Patient Ombudsman?

The 308 individuals in the county of Nordland who had chosen to contact the Patient Ombudsman gave the following reasons for this (many gave more than one reason) (Table 5.3a):

Table 5.3a: Reasons for contacting the Patient Ombudsman

Reason:	Number	Percentage
To complain about possible bad treatment	232	33 %
To get more treatment /another examination	107	15 %
To get more information	62	9 %
To have (copy of) my own record	49	7 %
To complain about arrogant conduct	131	19 %
To complain about routines etc. in the hospital	86	12 %
Other	33	5 %
Total	700	100 %

The table indicates that many patients contact the Patient Ombudsman for medical reasons or reasons closely linked to medicine. Some 50 % complain of not receiving the expected examination/treatment or about failure of treatment. About 80% of these cases are linked to treatment; the need for

examination or further/another treatment, or more usually complaints about possible failures and faults, especially linked to injury. This breakdown seems to apply similarly for other Patient Ombudsmen.

The same 308 individuals also reported what they wanted to achieve through their contact with the Ombudsman. Many of them gave more than one reason. Their answers are summarised in Table 5.3b:

Table 5.3b: What kind of help people want from the Patient Ombudsman?

What kind of help	Number	Percentage
To get advice	124	17%
To get help having their case clarified	171	23%
To obtain compensation	87	12%
To get an admission of fault	139	19%
To prevent others encountering the same situation	118	16%
To get new examination/treatment	92	12%
Other	11	1%
Total	742	100%

The data tell us that the patients have different expectations. However, when as many as nearly 2/3 say they want their case clarified, it means that it is important for patients that health professionals communicate openly about what has happened in connection with treatment.

5.4. Assistance

The evaluation from the county of Nordland does not tell us what kind of assistance the patients got. The type of assistance from the Patient Ombudsmen in general is, however, in 2006 nationwide registered according to a special form[12]. Table 5.4 describes the different kind of assistance the Ombudsmen offers, and gives figures of this in percentages.

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(12) Data summed up on basis of the Annual Reports 2006 from the Patient Ombudsmen in Norway (only in Norwegian).

Table 5.4: What kind of assistance do people get from the Patient Ombudsman?

What kind of assistance	Percentage
Given advice	51%
Assisted patients applying the Patient Compensation Scheme for damages	18%
Dialog by letter with the hospital on behalf of the patient	13%
Verbal dialog with the hospital on behalf of the patient	4%
Assisted patients sending complaints to the National Board of Health Supervision	2%
Others	12%
Total	100%

This figures show that the Ombudsmen in about half of the cases give advice of different kind without involving himself in direct contact with others than the patients/their relatives. In some of these cases we know the Ombudsmen recommend the patients to seek legal advice. In the group "others" we find many cases where the Ombudsmen get information of more general kind about problems in hospitals, and make different use of data about this. In the rest of the cases the Ombudsmen assist the patients directly following up their complaints contacting the hospitals or staff there, applying the System of Compensation to Patients for damages, and/or by sending cases to the supervisory authority for evaluation. Many cases thus are also taken on to institutions outside the secondary health care to reach a final solution or decision.

Whether enquiries are investigated, what kind of further approach is taken, and what kind of concrete follow up is made, seems to vary some among the Ombudsmen[13], e. g. depending on their interpretation of their role. Ombudsmen who are lawyers seem to tend to support patients well on legal matters, while others partly may (feel they) lack competence to do so and support patients more in other ways. The figures form the different Ombudsmen have, however, to be analysed more over time to give reliable information about this.

From the evaluation in Nordland we have information about how satisfied the patients were with the support they received. About 75% responded that the time taken for the Patient Ombudsman to finish an investigation was

(13) The Annual Reports 2006 from the Patient Ombudsmen in Norway (Only in Norwegian).

not too long. Some 60 % were more satisfied than dissatisfied with the kind of help that they had received. Likewise slightly more than 60% considered that their case had been sufficiently analysed. However, about 40% felt that the Ombudsman showed unduly more consideration for the hospital and the health personnel. In another evaluation in the county of Nordland 68% said that the ombudsman had been of great support, 24 % that it had been of some support, whilst only 8% said that assistance given had been of little or no help.

Evaluations were also carried out in other counties through the 1990's. They have yielded more or less the same results, though some have been more favourable to the Patient Ombudsman. Indeed, no evaluations were such as to recommend finishing the existing Ombudsman arrangement or special measures to change it in a radical way. When the Ministry of Health and Care Services summarised countrywide experience of the Patient Ombudsmen towards the end of the 1990s, the fact that most patients seemed to be satisfied with their work was emphasised[14].

5.5. The effect of the ombudsman's intervention

We have no general data describing in detail the effect of the Ombudsman. However, separate small evaluations indicate that the Ombudsman play an important role. Patients have to a great extent obtained further examinations, further treatment, more information, copies of their records, and compensation and ex gratia payments they would otherwise not have obtained[15]. For example an evaluation from the State University Hospital in Oslo in the beginning of the 1990s concluded that over a two-year period patients at that hospital had received a total of more than 2 million USD in economic compensation that they probably not would not have been paid if the Patient Ombudsman scheme not had been in place[16].

In the county of Nordland 226 health personnel engaged in secondary health care services have answered some questions about their opinion of the Patient Ombudsman Scheme. First they were asked to relate what effect they thought the Ombudsman had on them and on the hospital. Of the 226 respondents some 50 % said this was a necessary supplement to the existing safeguard measures, while 10 % said they considered it unnecessary to have

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(14) Proposition nr. 12 (1998-99) to the Odelsting (Parliament). "About the Act on Patients' Rights, chapter 8. (Only in Norwegian)

(15) MOLVEN, O. Patient Ombudsman at the State University Hospital. Experience with a 2-year trial. Tidsskr. Nor. Laegeforening. *The Journal of the Norwegian Medical Association*, v. 109, n. 24, p. 2457-60, 1989. (In Norwegian with English summary)
MOLVEN, O. The Patient Ombudsman Scheme — A Contribution to Legal Safeguards and Quality in the Health Service?, cit., p. 195-222 (Only in Norwegian).

(16) FALLBERG, L.; MACKENNEY, S. *Op. cit.*, p. 343-357.

an ombudsman. Nearly half the group said that the existence of the Ombudsman made it more important for them to exercise internal professional controls than had been the case before. Likewise nearly 60% said that the internal control routines in the hospital had become more important.

These health personnel were also asked to evaluate what effect they thought the Ombudsman scheme had had in general, (not just their specific experience in Nordland), in terms of supporting patients' interests and legal rights. As much as 87% said that this was important/very important, while only 13% considered it not important. It appears health personnel consider the Patient Ombudsman scheme to be positive and have the view that it is an important factor in safeguarding patients' interests and legal rights.

5.6. Co-operation between the Patient Ombudsmen

The Patient Ombudsmen work in a decentralised way, and some of them work alone. To some extent they have different professional qualifications. They (therefore) may tend to choose different roles and use different methods. To respond to this, the Ombudsmen in recent years have on their own initiative arranged annual meetings to discuss common issues and problems; share and exchange experiences; and discuss working methods. Likewise some of them meet regionally a few times a year to assist each other in resolving difficulties. Many of the Ombudsmen consider these meetings give them important new input into their practice. In addition to the web site of each of the Ombudsmen they have a common web site. In recent years they also have co-ordinated their statistics, however, here are still some to do to have sufficient comparable data.

5.7. Discussion

In 2006 more than 11000 patients got in touch with the Patient Ombudsman while the Civil Ombudsman yearly receives about 50 requests regarding health. It is seen as easy for patients to contact the Patient Ombudsmen. The caseload of the Patient Ombudsman concerns mainly medical problems linked to treatment, and in particular complaints about bad outcomes or injuries sustained. Procedural questions play also a role. The problems are dealt with in different ways, and many patients get active support from the Ombudsmen in presenting their cases to the health services.

The figures from the county of (capital) Oslo indicate that patients are in need of assistance just as much in primary care as in connection with secondary health care. This may possibly differ outside Oslo, but there are no specific reasons to think so. This system should be evaluated, perhaps by a project where the Ombudsman in an average county like Nordland has his

functions extended to cover primary health care. Such a project seems however now not longer of interest as the Ministry of Health and Care Services, according to the experience from Oslo, already has said that they will propose that the Ombudsmen in the future also shall have primary health care as a sphere of their authority.

Most patients are satisfied with the help they get from the Patient Ombudsman. However a number also seem not to be so. This may be linked to the fact that the Ombudsman does not fulfil his functions properly. Some of the Ombudsmen work alone and do not get the supervision they may need to make an optimal job. Likewise the personalities involved and their professional skills may vary and not be sufficient. A reason for dissatisfaction may on the other side be that many patients have unrealistic expectations about what can be done. The experience of Norwegian Board of Health Supervision officers handling complaints is also that patients often have out of reach expectations. This point of view may be supported by the fact that only about one-third of the complaints are successful for patients making claims before the National Board of Health Supervision or the System of Compensation to Patients.

Health personnel seem to regard the Patient Ombudsman Scheme as an important safeguard for patients. It is not quite clear why this is the case, however, over time it seems like health personnel have become more positive to the Ombudsmen. Their functions must then have been seen important to the patients. Health personnel may on the other hand, however, also fear that the Ombudsman will create extra burdens or even create trouble for them, perhaps without real grounds. This is not a wholly unusual point of view, but it is unlikely now to be a significant issue for health care workers.

It is important in itself for patients to know that they have someone in a formal position like the Patient Ombudsman to contact when they need assistance. In the end, however, it is concrete results for patients from their requests for advice or an investigation that count the most. Evidence from specific evaluation exercises and studies, of some is referred to, indicates that the Ombudsman scheme provides concrete results that patients would not have obtained without the Ombudsman's intervention.

The Patient Ombudsmen several times address general concerns to the hospitals. We do not know in detail from written material what kind of results this or other more general activities of the Ombudsmen have achieved. However, there are many statements in the annual reports indicating that the Ombudsmen have played an important role in changing systems to ensure the quality of health service. Some of the Ombudsmen also participate regularly in the hospitals' quality committee meetings.

6. ANALYSIS

Complaints from patients can be submitted at the level of the medical institution where health care is delivered [the municipalities, the health care enterprises (hospitals)]. If patients believe that their legal rights have been violated, they may also complain to the National Board of Health Supervision that has the power to reverse a decision made by the medical institutions and also to correct and discipline health personnel and institutions. If patients believe they are entitled to compensation, they may make requests to the Patient Compensation scheme. Patients who think they need assistance from others to have their needs, interests and legal rights met by the health care enterprises (the secondary health services), or need assistance contacting or presenting cases before the National Board of Health Supervision or the System for Compensation to Patients, may seek and get such assistance from the Patient Ombudsman.

The Patient Ombudsman hold today a rather strong position in local communities, and in this respect have truly benefited to some extent from the already established reputation of the Civil Ombudsman. The Patient Ombudsman institution is now generally well accepted by hospital administrators, physicians and nurses. Problems presented for the Ombudsman often find their solution on a local level. There is also reason to believe that the Ombudsmen also have benefited from the position that cases brought to them involving injuries to patients very seldom find their way to the courts. Since such cases tend to end up within the Patient Compensation scheme the patient injuries represent far less of a confrontational approach to the health professionals. However, it is still a challenge that the Ombudsman shall report serious cases or situations to the supervisory authority.

In the introduction above is set out some basic elements that some 15 years ago (five years after the first Patient Ombudsmen schemes started) were considered necessary for a well-functioning Patient Ombudsman scheme. Many of these elements have now been put into practice: The scheme is regulated by law and is organised regionally. The help is free of charge; the Ombudsman carries out his work independently and has no other roles besides working as an Ombudsman. Some elements are, however, not fulfilled: The Ombudsman has still only the specific remit of secondary health care services as their field of work. The general trend in recent years in Norway has been to use legislation in underpinning patients' interests, however there is still no regulation conferring *legal* training or competence on the Ombudsman.

Information and evaluation exercises from the late 1990s tell us that the Patient Ombudsmen themselves seems to have differing attitudes towards their role. Some state that they act more as lawyers, some as intermediaries, some as spiritual advisers, and some state that they mix these roles. In spite of the new legislation, the Ombudsmen in different counties, according to the

statistics about handling the cases, still seem to undertake a bit various roles. This may follow on from local traditions, local guidelines and their personal training — and should be more investigated.

The role of the Patient Ombudsman should be developed. This is more important since all the Ombudsmen do their work under a common law. They need at the very least an organisational body or a forum that can develop and shape their future role. We should be able to expect that every Ombudsman will generally take the same action in the same situations. Some functions are common to all systems today, but some Ombudsmen will have, according to the statistics from the annual reports, to modify their practice to come into line with standard practice that should be something like this:

> "The Ombudsman ought first of all to act as a person helping patients, when they need informal support, to ensure that the relevant health service providers deal with their problems. In this way the Ombudsmen today seems to act similarly."

If the patient is dissatisfied with the answer given by the service provider or if the service provider does not want to take action in relation to *e. g.* examination or treatment, the Ombudsman should pursue the matter orally or by letter, and seek further information. Here the Ombudsmen probably differ some in their way of acting; some seems far more active than others.

If the Ombudsman is of the opinion that the service provider is breaking the law, this should be made explicit. Ultimately, the Ombudsman should help patients to complain to the National Board of Health Supervision. The figures about this activity indicate that the Ombudsmen act different.

If the health service provider does not wish to take action in the case of potential patient injury, the Ombudsman should ask the service provider for more information about the damage and additionally seek a copy of the relevant medical records. It must also be a part of his role to help the patient pursue a claim for damages with the Patient Compensation scheme if a compensation award may be appropriate. According to statistics the Ombudsmen seems to vary some in their behaviour.

Repeating problems that the Ombudsman experiences, should be brought before the hospital as a concern about quality more in general. Ultimately the National Board of Health Supervision is the addressee for this. Also here practice seems to differ among the Ombudsmen.

In the community the focus is frequently on whether the Ombudsman should act as "a lawyer or a bridge-builder". These are, however, often to be seen as two aspects of the same coin: either acting formally or informally. The answer is therefore not an "either-or". The focus should be on first of all using an informal approach, when this course of action is appropriate. If this line does not achieve results, then formal steps can or must be taken.

It may be a constant challenge to a Patient Ombudsman to meet different patients, health personnel and representatives and to find solutions acceptable for everyone. Bridge-building presupposes not only a specific attitude, but also personal skill. Individual qualities such as the ability to listen to other people, communication and conciliation skills are important. The Ombudsman needs also legal knowledge and training to enable him to operate as a negotiator. Taken altogether, Ombudsmen need a good deal of training to live up to the exacting requirements of this basket of qualifications.

Norway steadily introduces new legislation that gives patients increased rights. Likewise there are provisions giving patients new rights to make complaints and have health service decisions reversed. It is not yet evaluated what kind of impact this has had on the Patient Ombudsmen's operations, though it is expected that they will have more of a role in legal matters as patients begin increasingly to use their rights and have their cases. However, also in the future the Ombudsman should take on the role of bridge-builder. First when this route fails or is not appropriate, the Ombudsman must act much more as a lawyer, arguing the point or bringing the case to the right public forum, such as the supervisory authority and the Patient Compensation scheme.

Over time the Patient Ombudsman will collect information accumulated from individual case investigations that may be of great interest to hospitals, and ultimately to specific units in the hospitals. It is important that the Ombudsmen can identify problems that recur and try to ensure that the health service providers take action to deal with such problems. Ombudsmen should, as already experienced from some of them, on the basis of experience, alone or together with representatives from the hospitals, initiate and participate in studies that seek to investigate and understand such problems and try to identify the measures needed as a result.

The knowledge and the information the Patient Ombudsmen hold are highly relevant in education. It is a role for many of the Ombudsmen in practice to pass on their knowledge and experience to, for example, groups of health staff. As a part of this educational activity the Ombudsman can underline the fact that it is the health staff themselves with the principle duty to protect patients' rights and inform patients of these rights.

Though the Patient Ombudsman Scheme has worked in Norway some 20 years, and the last 7 of them under the Act on Patients Rights, there has, however, been no complete comparing evaluation the Ombudsmen focusing on what has functioned well and not so well in practice. Only some minor and limited evaluations have been worked out, as the one I have referred from the county of Nordland. To further develop the Patient Ombudsman institution in Norway, I think the first and best thing to do now is to carry through such a broad evaluation examining especially the Ombudsmen's way of working and the view of the view of the workin among patients and other persons/ institutions involved.

7. CONCLUSIONS — KEY ELEMENTS BUILDING A PATIENT OMBUDSMAN SCHEME

The Norwegian Patient Ombudsman scheme has developed over a period of more than 20 years, and the situation can be summed up like this: The scheme is well known among patients, and has a generally good reputation across the community. The Ombudsman is seen as a significant part of the system for ensuring that patients avail themselves of their rights and that the quality of the health services is improved. The scheme has a clear place amongst the health institutions, and has an important role in achieving solutions for patients in need of a mediator or a spokesman. A significant part of the Ombudsman's role is to emphasise and resort to legal measures when other approaches are inappropriate or have failed.

Based on experiences from different European countries, there have been commended ways to organize Patient Ombudsmen Schemes to make them effective as much as possible[17]. According to these recommendations the Norwegian scheme seems to be rather well developed; many of the elements building a system suitable for the purpose seems to be fulfilled: *E. g.* the institution is regulated in law, the Ombudsmen are full-time employed, work locally and independently, can investigate cases, and have unlimited access to patient records and evidence regarded as relevant, and reports from the investigations are made public. Also compared with Patient Ombudsman schemes in other European countries, the Norwegian scheme seems to a high degree to meet the requirements for having a system that serves patients in a proper way.

From the experience in Norway with the Patient Ombudsman Scheme of what has worked well and not so well, and in spite of having a total evaluation of the arrangement, I think it is right to conclude with the following recommendations as important building an effective scheme:

a) The Role of the Patient Ombudsman must be clarified and sufficiently published.

b) The Patient Ombudsman must be a professional.

c) The Patient Ombudsman must work independently.

d) The Patient Ombudsman may not at the same time work in any other role.

e) The Patient Ombudsman must help patients to avail themselves of their legal rights.

f) The Patient Ombudsman must primarily work in an informal way.

g) The Patient Ombudsman must have the authority to investigate cases.

h) The Patient Ombudsman must have power to access relevant documents.

i) The Patient Ombudsman must, if necessary, use the formal system to assist patients.

j) The Patient Ombudsman must give a written reason for not handling cases.

k) The Patient Ombudsmen should report their activities to the public.

l) The Patient Ombudsmen should co-operate between themselves and have a professional forum for doing so.

m) The Patient Ombudsman should aggregate data from the requests and investigations and use the data in their contact with hospitals and health authorities to contribute to the improvement of health services.

n) The Patient Ombudsman Scheme must have its basis in law.

o) The Patient Ombudsman Scheme must be publicly financed.

p) The Patient Ombudsman Scheme must be free of charge.

q) The Patient Ombudsman Scheme must be locally organized.

r) The Patient Ombudsman (staff) should have both legal and health competence.

s) The Patient Ombudsman Scheme must have publicity.

t) The Patient Ombudsman Scheme(s) must be regularly evaluated.